PILOT BIOPRODUCTION FACILITY (PBF)

SILVER SPRING, MD

The Pilot Bioproduction Facility (PBF) is a cGMP-compliant pharmaceutical manufacturing facility located in Silver Spring, MD, at the Walter Reed Army Institute of Research. It has 12,500 sq.ft. of process, labs and support areas, of which 9,000 sq.ft. is cleanroom space. Established in 1953 as the Department of Biologics Research, the PBF specializes in developing vaccines and biologics for military-relevant infectious disease threats. That mission has since expanded to include collaborations with public and private partners through cooperative agreements. Between 2016-2020, the PBF underwent extensive renovations to expand and improve its state-of-the-art capabilities. Limited GMP operations will resume at the end of June 2020*.

PILOT BIOPRODUCTION FACILITY BY THE NUMBERS

>20
productions per year

400L
production capacity per run

>5,000 vials
fill/finish capacity

75+
partners organizations

CAPABILITIES

- BSL-2 fermentation (up to 400 L scale)
- Harvest/cell separation
- Purification, conjugation
- Live virus production
- Harvest
- Inactivation and Purification
- Formulation & fill / finish, including lyophilization
- Support areas / QC and QA
- Viral assays / clinical immunogenicity
- Stability studies
- Technology transfer
- Cell Banking

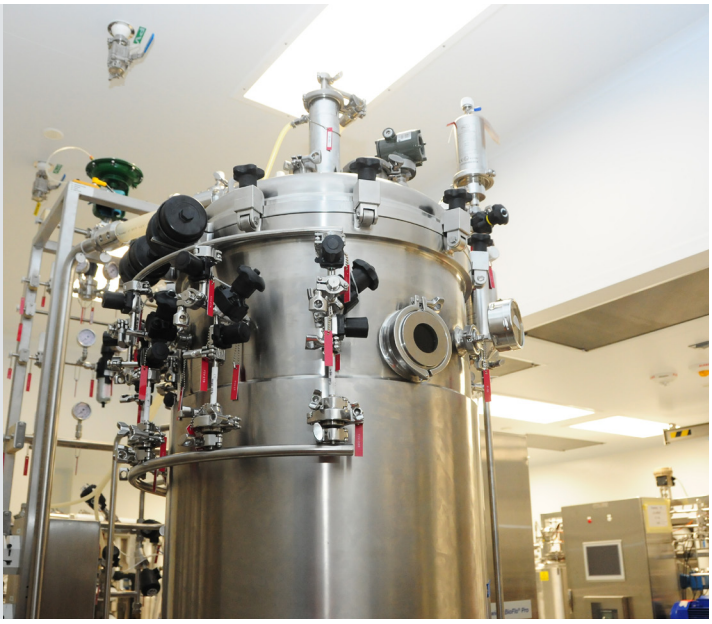
TYPES OF PRODUCTS

- Live, attenuated or inactivated bacterial/viral vaccines
- Purified protein vaccines
- Conjugate vaccines
- Bacteriophage production
- Bacterial/viral/parasite seeds
- Mammalian cells
- Microbial cells (yeast, bacteria, BSL-2)

*Timelines estimated based off of current clean core Certification schedule to obtain cGMP manufacturing capability.

PILOT BIOPRODUCTION FACILITY SUCCESSES

PBF support has been critical to the development efforts of the Department of Defense in the advancement of numerous vaccines. These vaccines include those for hepatitis A, meningitis, dengue fever, malaria, adenovirus, Japanese encephalitis, shigellosis, and, most recently, Zika. Several of these experimental vaccines have progressed to advanced clinical testing and licensure.



PARTNERING TO BRING VACCINES TO THE CLINIC

A collaboration with the PBF brings decades of understanding and a track record of success in the manufacture of GMP and non-GMP batches of vaccines and biologics.

The PBF works closely with each client to facilitate smooth and efficient technology transfer. Our reliable manufacturing processes permit timely regulatory filings and effective clinical trials. Experienced staff and state-of-the-art equipment, including classified-air cleanroom spaces, assure reliable production with compliance and safety as top priorities.

Through our decades-long history, we have successfully worked with a diverse array of collaborators, from government and military facilities to academic institutions and biopharmaceutical enterprises of all sizes.

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CASE STUDY: ENABLING A BACTERIAL CONJUGATE VACCINE TO ENTER THE CLINIC

Starting Material
Research Grade Starting Material submitted

Cell Banks
Master and Working Cell Banks are manufactured

Fermentation, Harvest, Lysis
Cells are harvested by microfiltration and centrifugation, and then lysed

Purification / Conjugation
Cell paste is purified into a bulk vaccine and conjugated

Formulation and Fill
Bulk vaccine is formulated and dispensed into vials

Quality Control
The vaccine is tested, then released for use in approved human clinical studies